US ERA ARCHIVE DOCUMENT

September 20, 2012

21st Century Toxicology/New Integrated Testing Strategies Workgroup Meeting

Time: 1:00 – 3:00 PM (EST) Conference room: 8621 Potomac Yards South

Call in number: 1-866-299-3188; 703-308-0293 # **Adobe Connect:** https://epa.connectsolutions.com/ppdc_21c/

Agenda

1. Welcome – Jennifer McLain

- 2. Metric Proposal At our last meeting the metrics subgroup presented a proposal to revisit, augment and implement metrics for progress on *in vitro* testing by setting specific goals and measuring progress to achieve these goals in the context of acute hazard labeling studies. At this meeting EPA will present baseline data on the number of *in vitro* and *in vivo* acute toxicity tests submitted to the Agency in FY 2008 FY 2012 for discussion on incorporation into the metrics proposal.
- 3. Revised Future FACA Proposal Erik Janus will lead a discussion on an updated draft proposal for a 2-day FACA meeting in Spring 2013 focusing on Tox21 tools currently being utilized and/or considered by EPA.
- 4. Biomarker Definitions As a result of the October 2011 biomarker workshop and questions from the PPDC, OPP has worked with ORD to develop a set of biomarker definitions for the workgroup's webpage. The goal of these definitions is to provide clarity on biomarker terminology. At this meeting EPA will present the draft definitions for the considerations of the workgroup.
- 5. List of Proposed Subject Matter Experts for Development of a Priority Pesticide List The workgroup has developed a list of experts to be approached to participate in a series of conference calls with the goal of developing criteria for determining priority pesticides and constructing a list of priority pesticides that could be used to inform future biomarker research.
- 6. Other Topics

General Notes

Subgroups:

• <u>Biomonitoring:</u> Develop a priority list of pesticides for biomarker research. Identify how existing data relevant to diagnosing overexposure to pesticides can be made more accessible and explore opportunities for additional information.

Lead = Jimmy Roberts & Cheryl Cleveland Members = Matt Kiefer, Amy Liebman, Erik Janus, Caroline Cox, Valentin Sanchez, Virginia Ruiz and Cindy Baker Smith

• <u>Future FACA</u>: Develop and plan future workshop to support OPP's communication on and transition to 21st C science.

Lead = Erik Janus

Members = Kristie Sullivan, Kate Willett, Tim Pastoor

• Metrics: Create a proposal to OPP for measuring progress on *in vitro* testing.

Leads = Kristie Sullivan, Kate Willett

Members = Pat Bishop, Cheryl Cleveland, Caroline Cox, Jennifer McLain, Joel Patterson, Pat Quinn, Tom Kellner

OPP Charge to Subgroups on Biomonitoring:

- 1. Develop priority list of candidate pesticides for developing human health pesticide biomarkers for research and clinical applications. Convene expert group and agree upon criteria for developing list.
 - a. OPP will work with subgroup to identify and contact experts.
 - b. OPP will coordinate calls with expanded subgroup.
- 2. Create pesticide use case(s) for submission to DARPA as well as other research programs (e.g., NIEHS, EPA ORD) to encourage funding for research on rapid diagnostic methods for pesticides to enable clinical trials and point-of-need diagnostics.
 - a. OPP will work with subgroup to develop use case(s) i.e., pesticide exposure scenarios (background on the DARPA project attached below; see also email from Erik J 5/21/2012).
 - Consider priority exposure and clinical diagnostic scenarios associated with chemicals on the priority pesticide list.
- 3. Identify existing data relevant to diagnosing overexposure to pesticides
 - a. OPP will inquire with EU/EFSA regarding availability of biofluid analytical methods and criteria EU uses to determine when biofluid methods are necessary.
 - b. Subgroup will determine if information on existing biofluid analytical methods should be incorporated into pesticide use case(s).
 - c. Review WHO guidance "Triage and clinical management of patients with acute pesticide self-poisoning presenting to small rural hospitals".
- 4. Subgroup will identify whether information on existing data relevant to diagnosing overexposure to pesticides and/or information from the WHO guidance should be included in future versions of Physician's Handbook.